

REMARKS

Claims 1, 3-12, 14-25, and 27-51 will be pending upon entry of this Amendment B and Response After RCE. Claim 1 has been amended to require the single-use lip treatment product to comprise from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. Support for this amendment can be found in originally filed claim 2 and, further in the instant Specification at paragraph 21. Additionally, Claims 31-48 and 50 have been withdrawn as directed to a non-elected invention. Applicants expressly reserve the right to file divisional applications directed to these non-elected claims.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claim 51 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claim 51 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755).

Claim 51 is directed to a single-use body treatment product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material, from about 0.01% by weight to about 50% by weight of a moisturizing agent, and from about 0.1% by weight to about 50% by weight of a solidifying agent. The single-use body treatment product is a film and further comprises a single layer.

Fox discloses a water soluble sheet or film for use in the personal care field. The water soluble sheets include a "base

composition" that includes from about 0.75% to about 5% by weight of a water soluble film forming polymer; from about 6.5% to about 23% by weight of polyvinyl alcohol; and from about 0.75% to about 12% by weight of a humectant such as propylene glycol.¹ Suitable materials for use as the water soluble film forming polymer include polyvinylpyrrolidone (PVP), polyquaternium 10, magnesium aluminum silicate, VP/VA copolymer, ethyl ester of PVM/MA copolymer, and sodium magnesium silicate.² Furthermore, the base composition can be used with a variety of surfactants, which when exposed to water, will dissolve and provide personal cleansing such as can be obtained from a soap bar or a liquid body wash.³

As noted by the Office, the Fox reference fails to specifically teach or suggest a composition having the recited components in the specific weight percentages as claimed in Applicants' claim 51. The Office, however, states that Fox discloses a composition having components that meet and/or overlap with the ranges as claimed and, further, states that it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the ingredients provided in the composition to arrive at Applicants' claim 51. Furthermore, in the final Office action, the Office states that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product, and thus, the final sheet product can be expected

¹ U.S. 2004/0071755 at paragraph 9.

² *Id.* at paragraph 10.

³ *Id.* at paragraph 6.

to have a higher percent by weight of each of the components due to the loss of water in the drying process.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some combinations would have been obvious where others would not.⁴ The Office has clearly failed to meet its burden under numbers (1) and/or (2) above, as the cited reference does not teach or suggest all of the claimed limitations and there is no apparent reason to modify the reference to arrive at each and every limitation of Applicants' claim 51. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, as recognized by the Office, Fox fails to teach or suggest a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. This is a significant aspect of Applicants' invention.

⁴ Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) See also KSR Int'l Co. v. Teleflex, Inc., et al. 550 US_____, 2007 WL 1237837 at 12 (2007).

There is simply nothing in Fox stating that its compositions as disclosed should comprise from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. Nor is there any reason for one skilled in the art, reading Fox to modify the compositions described therein to arrive at a composition that comprises from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material.

As noted above, the compositions of Fox comprise from about 0.75% to about 5% by weight of a water soluble film forming polymer (e.g., polyvinylpyrrolidone) and from about 6.5% to about 23% by weight of polyvinyl alcohol, which are listed as examples of water-soluble film forming polymeric materials in Applicants' claimed invention. As such, the maximum amount of water-soluble film forming polymeric material for use in the composition as taught in the Fox reference is 28% by weight. Furthermore, as shown in all of the working Examples in the Fox reference, the water soluble film forming polymer is present in the base composition in an amount of about 15.66% by weight (i.e., 1.75% PVP K-30 + 13.91% AirVol 523S (polyvinyl alcohol)). More specifically, the final products produced in the working Examples of the Fox reference teach even lower amounts of water soluble film forming polymers. Specifically, the working Examples show that the base composition is present in the final composition in amounts of from about 19.5-21% by weight. Thus, the compositions set forth in Fox have significantly lower percentages of water-soluble film forming polymeric materials than the products set forth in Applicants' claim 51. Based on this disclosure, there is no apparent reason for one skilled in

the art to avoid preparing the compositions of Fox having less than 40% by weight of water-soluble film forming polymeric material, in direct opposition to the products set forth in Applicants' claim 51.

Furthermore, while the Applicants recognize that the base composition is dried onto the final product, no where in the cited reference is it taught or suggested to what extent the base composition is dried. Specifically, no where in Fox is the final water content of the product disclosed. As such, there is no teaching or suggestion that enough water is removed during the drying process to result in the final product comprising from about from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material as required in claim 51.

Moreover, the common sense of one ordinarily skilled in the art would not have provided a reason to modify the Fox reference to arrive at Applicant's treatment product of claim 51. Specifically, as recognized by the Supreme Court in KSR International Co. v. Teleflex, Inc., "while an obviousness determination is not a rigid formula, the TSM (teaching, suggestion, motivation) test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to [modify] the elements as the new

invention does.”⁵ More particularly, a court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions. If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability. For example, in KSR, the patented invention was directed towards an improved adjustable vehicle pedal assembly, and, as has long been held in the Federal Circuit, mechanical arts are predictable.⁶ Recognizing that mechanical devices such as adjustable vehicle pedals and sensors can be predictably modified and combined by one skilled in the art, the Court invalidated the patent as obvious.⁷

By contrast, areas of chemistry, such as in the instant case of Applicant’s treatment products, have been held inherently unpredictable. Specifically, as stated in *In re Marzocchi*,⁸ “in the field of chemistry generally, there may be times when the well-known *unpredictability* (emphasis added) of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of [generalized] broad statements.” That is, chemical reactions are, by their nature, unpredictable

⁵ *KSR Int’l Co. v. Teleflex, Inc., et al.* 550 US ___, 2007 WL 1237837 at 5 (2007).

⁶ See MPEP §2164.03 (*citing* *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971)); *See also*, *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991).

⁷ *KSR Int’l Co. v. Teleflex, Inc., et al.* 550 US ___, 2007 WL 1237837 at 17 (2007). Specifically, the Court held that there was convincing evidence that mounting a modular sensor on a fixed pivot point of a pedal was a design step well within the foreseeable grasp of a person of ordinary skill in the relevant art and, as such, the claimed adjustable pedal assembly of claim 4 was obvious.

⁸ 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971).

and, as such, generalized or broadly disclosed elements cannot necessarily be predictably modified.

As there is no teaching or suggestion as to the amount of drying of the final product and the relative percentages of the components of the base composition in the dried product and, further, chemical reactions are inherently unpredictable, there is no disclosure or suggestion to provide the necessary reasoning needed by one of ordinary skill in the art to modify the amounts of a water-soluble film forming polymeric material to arrive at the specific composition in the treatment product as required in claim 51.

As Fox fails to disclose compositions comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material as required in claim 51, and further, there is no apparent reason for one skilled in the art to modify the compositions of Fox to arrive at the compositions of claim 51, claim 51 is patentable over the Fox reference.

2. Rejection of the Claims 1-12, 14-18, and 49 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-12, 14-18, and 49 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755) in view of Akihiro, et al. (JP 11-209222), and further in view of Kyoko (JP 61-176512).

Claim 1, as amended herein, is directed to a single-use lip treatment product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material, from about 0.01% by weight to about 50% by weight of a

moisturizing agent, and from about 0.1% by weight to about 50% by weight of a solidifying agent. The single-use lip treatment product is a film and comprises a single layer. The product is capable of being substantially dissolvable on lips in no more than about 50 seconds. Furthermore, the single-use lip treatment product is sized and configured for application to the lips.

Fox is discussed above. Significantly, Fox fails to disclose a composition having the recited components in the specific weight percentages as required in claim 1. Specifically, Fox fails to teach or suggest a product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. Furthermore, Fox fails to disclose that its final product is sized and configured for application to the lips and is capable of substantially dissolving on lips in no more than about 50 seconds as required in amended claim 1. Recognizing that Fox fails to teach or suggest each and every limitation of Applicants' claim 1, the Office attempts to find each and every element of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness by citing the Akihiro, et al. and Kyoko references for combination with Fox.

Specifically, Akihiro, et al. disclose a humectant pack material for lip treatment. The pack material includes a polymer gel containing from 0.01 to 80 wt.% humectant and from 10 to 95 wt.% water in a polyacrylamide-based polymer.⁹ The polymer gel is obtained by carrying out a water-soluble

⁹ JP 11-209222 at abstract.

polymerization of an acrylamide-based monomer with an acrylic-acid (meta) amide. Specifically, a cross-linking acrylamide monomer such as N and N'-methylenebis acrylamide, methylenebis methacrylamide, and N'N, N'-ethylene screw acrylamide, [N, and] N and N'-ethylene screw methacrylamide, 1, and 2-JIAKURIRU amide ethylene glycol, is polymerized using an epoxy cross linking agent, such as ethylene glycol diglycidyl ether, polyethylene glycol, diglycidyl ether, triglycidyl 2 hydroxyethyl isocyanurate, trimethylolpropane polyglycidyl ether, glycerol poly glycidyl ether, and sorbitol polyglycidyl ether.¹⁰

The resulting polymer gel includes less than 0.3% by weight cross linking monomer and less than 3.0% by weight cross linking agent. The pack material including the polymer gel can be fabricated to be in the shape of a lip.¹¹ Furthermore, the pack material is designed such that the material is adhered onto the surface of the lip and then removed from the lip after a time period of from 0.1 to 10 minutes to provide moisturization.¹²

Significantly, no wherein in the Akihiro, et al. reference, is it taught or suggested for the pack material to be a water-soluble material (such as the material in the Fox reference, and further, in Applicants' claimed invention), capable of solubilizing on the skin for a suitable treatment thereof and, more specifically, no where is it disclosed that the pack material is substantially dissolvable on lips in no more than

¹⁰ See translation of *id.* at paragraph 10.

¹¹ See translation of *id.* at paragraphs 4 and 20. Specifically, as disclosed in paragraph 20, the configuration of the pack material can be an ellipse form, circular, a lip form, a heart form, a hemicycle, a half-ellipse form, a rectangle, etc.

¹² See translation of *id.* at paragraph 23.

about 50 seconds. While, as noted above, the polymer gel is obtained by carrying out a water-soluble polymerization; there is nothing to suggest that the resulting gel, and resulting pack material, is water-soluble. Moreover, as noted above, the gel must be removed from the surface of the skin after a short period of time has lapsed; that is, the gel will not substantially dissolve upon contact with moisture on the lips. As such, the pack material of Akihiro, et al. is not, and cannot, dissolve on lips in no more than about 50 seconds.

Further, as taught in paragraph 22 of the translated reference, the pack material suitably is configured to have a multi-layer structure. This is in direct opposition to the single layer required in claim 1 (and further, as desired for the composition of Fox, as indicated by the Office in the present Office action).

Kyoko discloses a film-forming agent comprising a polymeric compound; a humectant; and an oleaginous wax for providing moisture to lips, and to further prevent abnormal drying and chapping of lips.¹³ Examples of polymeric compounds that can be used to form the film-forming agent can include PVA, polyvinyl pyrrolidone, and CMC. Furthermore, the humectant has excellent moisture-retainability and is effective to give moistness to the dried skin and can be, for example, glycerol, propylene glycol, polyethylene glycol, and sorbitol. The oleaginous wax is effective in supplying the skin with a moderate amount of oil to prevent chapping of the skin. Suitable waxes include olive oil, jojoba oil, lanoline, and squalane. The skin film is applied to

¹³ JP 61-176512 at abstract.

the lip mucous membrane surface and then the skin film is peeled off of the surface of the lip, either prior to or after the film has dried, to treat the lips.¹⁴

Significantly, as with the Fox reference, Kyoko fails to teach or suggest a composition having from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. At best, Kyoko discloses using 15% or less by weight of a polymer such as poly (vinyl alcohol), polyvinylpyrrolidone, or cellulose.¹⁵ Additionally, no wherein in the Kyoko is it taught or suggested that its skin film is capable of substantially dissolving on lips in no more than about 50 seconds. Similar to the Akihiro, et al. reference discussed above, the film must be peeled from the surface of the lip after a short period of time has lapsed, either prior to or after the film has dried to the surface of the lip; that is, the film will not substantially dissolve upon contact with moisture on the lips.

As noted above, in order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. As

¹⁴ See *Id.* (translation) at page 5, lines 9-16.

¹⁵ See, e.g., *Id.* at Examples 1-5. Specifically, water-soluble film forming polymers are present in the compositions in the concentrations as follows: Example 1: 15% by weight; Example 2: 15% by weight; Example 3: 13% by weight; Example 4: 15% by weight; and Example 5: 15% by weight.

further noted above, this is not a rigid formula as the common sense of those skilled in the art can demonstrate why some combination would have been obvious where others would not. The Office has clearly failed to meet its burden under numbers (1) and/or (2) above, as the references, alone or in combination, fail to teach or suggest each and every element of claim 1 and, further, there is no apparent reason for one skilled in the art to combine and/or modify the cited references to arrive at Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Specifically, none of the cited references, alone or in combination, teach or suggest a film product comprising from about 40% by weight to about 70% by weight of a water-soluble film forming polymeric material. Furthermore, none of the cited references teach or suggest a film product that is capable of substantially dissolving on the lips in no more than about 50 seconds. Specifically, while both the Fox and Kyoko references disclose water-soluble film forming polymers, the cited references teach using amounts significantly lower than required in the instant claim 1.

Furthermore, while the film of the Fox reference can dissolve when exposed to water, the film dissolves to provide for a personal cleansing product such as in the form of a hand soap or body wash, which is then rinsed from the skin.¹⁶ No where is it suggested that the film can treat and/or moisturize the skin by substantially dissolving on the skin's surface in no

¹⁶ See U.S. 2004/0071755 at paragraph 5.

more than about 50 seconds. There is simply no suggestion in the Fox reference that the film can substantially dissolve in no more than about 50 seconds for treatment.

The Akihiro, et al. and Kyoko references fail to overcome the above shortcomings. Specifically, as noted above, no wherein in the Akihiro, et al. or Kyoko references is it taught or suggested that their products are capable of substantially dissolving on lips in no more than about 50 seconds. More particularly, in direct opposition to claim 1's requirement of the film being capable of substantially dissolving on the lips, the cited references both require that their products be physically peeled or otherwise removed from the surface of the lips to provide treatment. As such, none of the cited references teach or suggest a film product being capable of substantially dissolving on lips in no more than about 50 seconds.

Furthermore, Applicants assert that there is no reason or motivation present in either the cited references or in the general knowledge of one ordinarily skilled in the art to combine and/or modify the cited references to arrive at each and every limitation of claim 1. Specifically, a close reading of the references actually teaches away from the combination as the compositions and products produced in the cited references are designed to solve different problems using different mechanisms. For example, as noted above, to treat the lip/skin using the polymer gel of the pack material of Akihiro, et al. and/or the skin film of Kyoko, Akihiro, et al. and Kyoko teach applying their products to the lip surface, and further peeling the

material from the surface after a short period of time.¹⁷ As such, one skilled in the art, reading the Akihiro, et al. and Kyoko references, would not, and could not, reasonably use the polymer gel of Akihiro, et al. nor the film of Kyoko in the compositions of the Fox reference, which are designed to dissolve in water to produce a body cleansing product for cleaning the surface of the skin.

Furthermore, as noted above, the pack material of Akihiro, et al. suitably is configured to have a multi-layer structure. This is in direct opposition to the single layer as desired for the composition of Fox.

In the final Office action, the Office states that Applicant's arguments that Akihiro et al. fails to teach a water-soluble material in the moisturization pack for dissolving on the lips of a user and fails to teach that the pack is configured to a single layered structure are not persuasive as the Akihiro et al. reference was not used to address those particular limitations. With all due respect, Applicants disagree and note that the Office is combining the first two prongs of a *prima facie* case of obviousness under MPEP §2143. Specifically, the fact that the Akihiro et al. reference does not teach a water-soluble material in the moisturization pack for dissolving on the lips of a user goes to the second prong; that is, to the reason for combining the Akihiro et al. reference with the Fox reference. Specifically, as Fox is directed to using a base composition that dissolves when contacted with water, one skilled in the art would not

¹⁷ See JP 11-209222 at column 2, lines 32-42, and JP 61-176512 at page 5,

reasonably think to add the components of the composition in Akihiro et al., directed to a composition that is not intended to dissolve in water. Similarly, the fact that Akihiro et al. fail to teach a single layered structure also goes to the second prong of a *prima facie* case of obviousness. Specifically, as Fox is directed to a single layer product, one skilled in the art would not reasonably look to a product having a multi-layered structure.

As the references, alone or in combination, fail to teach or suggest all of the elements of amended claim 1 and, further, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1, claim 1 is patentable over the cited references.

Claims 3-12 and 14-18 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Claim 49 is similar to claim 1 and further requires a water-dispersible film forming polymeric material in combination with the water-soluble film forming polymeric material. As such, claim 49 is patentable for the same reasons as set forth above for claim 1 as well as for the additional elements it requires.

3. Rejection of the Claims 19-25 and 27-30 under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 19-25 and 27-30 under 35 U.S.C. §103(a) as being unpatentable over Fox (U.S. Application Publication No. 2004/0071755) in view of Akihiro, et al. (JP 11-209222) and Kyoko (JP 61-176512), and further in view of Yang et al. (WO 03/030881).

Claim 19 is similar to claim 1, as discussed above, and further requires the water-soluble film forming polymeric material to be pullulan and the moisturizing agent to be glycerin.

The Fox, Akihiro, et al., and Kyoko references are discussed above. Significantly, as discussed above, the Fox, Akihiro, et al., and Kyoko references fail to teach or suggest a product that is capable of substantially dissolving on lips in no more than about 50 seconds. Additionally, as noted by the Office, the Fox, Akihiro, et al., and Kyoko references fail to teach or suggest the specific water-soluble film forming polymeric material being pullulan as required in claim 19. Furthermore, the above cited references fail to provide a reasoning for combining the references to arrive at each and every limitation of Applicants' claimed combination. Yang et al. fail to overcome the above shortcomings. Specifically, Yang, et al. fail to provide motivation or reasoning for combining the cited references to arrive at Applicants' claimed invention.

Yang, et al. disclose an edible, ingestible water-soluble delivery system in the form of a film composition. The film composition comprises a glucan, such as pullulan, and a water-

soluble polymer. Furthermore, the film composition can contain a polar solvent and a pharmaceutical active such as for administration to a body surface including a mucous membrane, such as oral, anal, vaginal, ophthalmological, surface of a wound, such as during surgery, and similar surfaces.¹⁸

Significantly, Yang, et al. fail to teach or suggest a film product that is capable of substantially dissolving on lips in no more than about 50 seconds. Even more specifically, nowhere in Yang, et al. is it taught or suggested that their delivery system can even treat and moisturize lips, which is the specific problem to be solved in the other cited references (as well, as in Applicants' claimed invention). Specifically, as noted above, Yang, et al. is directed to edible, ingestible systems for delivering an active ingredient. As such, there is nothing in the Yang, et al. reference or in the general knowledge of one ordinarily skilled in the art, that provides for an apparent reason to use the **edible** delivery system of Yang, et al. with the **lip moisturizing** compositions and products of the Fox, Akihiro, et al., or Kyoko references.

Furthermore, as with the Akihiro, et al. reference discussed above, the delivery system of Yang, et al. is suitably a multi-layered film. This is in direct contrast to the composition of Fox. As such, one skilled in the art would actually be taught away from combining the Yang, et al. reference and the Fox reference.

As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every

¹⁸ WO 03/030881 at pages 6-7, lines 32-2.

limitation of Applicants' claim 19. As such, claim 19 is patentable over the cited references.

Claims 20-25 and 27-30 depend directly from claim 19 and are thus patentable for the same reasons as set forth above for claim 19 as well as for the additional elements they require.

CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-12, 14-25, 27-30, 49, and 51 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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